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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,039	12/20/2000	Raghu Raghavan	723.100US1	7943
7590	03/16/2004			
Mark A. Litman & Associates, P.A. York Business Center, Suite 205 3209 West 76th St. Edina, MN 55435			EXAMINER LU, TOM Y	
			ART UNIT 2621	PAPER NUMBER

DATE MAILED: 03/16/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,039

Applicant(s)

RAGHAVAN ET AL.

Examiner

Tom Y Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 35-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-34, drawn to a method for supplying a unified suite of quantification functionality for density functions defined in a three-dimensional space, classified in class 382, subclass 128.
- II. Claims 35-37, drawn to a method for affecting a therapy upon a patient, classified in class 600, subclass 411.

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because claim 35, which is the broadest combination claim, does not require the particular of Claim 1, the broadest subcombination claim. The subcombination has separate utility such as a method for supplying a unified suite of quantified functionality for density functions defined in a three-dimensional space.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark Litzman, Reg. 26,390 on 12/19/2003 a provisional election was made without traverse to prosecute the invention of I, claims 1-34.

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Affirmation of this election must be made by applicant in replying to this Office action. Claims 35-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

- a. Referring to Claim 1, the claimed density functions are mathematical functions, which have been held to be nonstatutory because they represent a mathematical definition of a law of nature or a natural phenomenon.
- b. With regard to Claim 2, see explanation in Claim 1.
- c. With regard to Claim 3, see explanation in Claim 1.

Claim Objections

2. Claim 1 is objected to because of the following informalities: "Computing" is misspelled as "computatiing". Appropriate correction is required.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 1-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Kucharczyk et al (U.S. Patent No. 6,061,587).

- a. Kucharczyk discloses two services selected from the group consisting of: (a) computing of the volume of a region where a density lies above a specified threshold, below a specified threshold, or between two specified values; (b) computing of an integral of a density; (c) estimating of a rate of change of a density with respect to time; (d) estimating of a local or global failure of conservation of a superstate within the region represented by changes with time in density; (e) estimating of a local or global rate at which material within a changing density is passing through a specified surface within the region or at a boundary of the region; (f) and separating of density of a material into free and bound densities with a changing density (Kucharczyk teaches two services of “estimating of a rate of change of a density with respect to time”, column 16, line 61, and “estimating of a local or global rate at which material with a changing density is passing through a specified surface within the region or at a boundary of the region”. Column 16, line 61, “0.1-10 $\mu\text{l}/\text{min}$ ” is global rate, column 20, line 67, “0.01 $\mu\text{l}/\text{min}$ to 10 $\mu\text{l}/\text{min}$ ” is local rate. column 18, lines 61-62, teaches “a

target anatomical location” is the claimed “a specified surface within the region or at a boundary of the region”, also see column 10, lines 22-25. Note the claims dependent upon unselected services will not be examined).

- b. Referring to Claim 2, Kucharczyk teaches wherein the density function in at least one service varies in time (column 11, lines 34-36).
- c. With regard to Claim 3, the claim is not examined because it is dependent upon one of the unselected services.
- d. Referring to Claim 4, Kucharczyk discloses wherein service c is restricted to a specified region (column 18, lines 61-62, “a target anatomical location”).
- e. With regard to Claim 5, the claim is not examined because it is dependent upon one of the unselected services.
- f. Referring to Claim 6, Kucharczyk discloses wherein estimation of the global rate or local rate at which a superstrate with a changing density is passing through a specific surface is performed within an implemented transport model (see figure 2 for transport model).
- g. Referring to Claim 7, Kucharczyk discloses wherein at least two services used in the method each yields an answer for restriction of a density to specified region (column 10, lines 22-25).
- h. Referring to Claim 8, Kucharczyk discloses wherein a density is obtained by a three-dimensional scanning process (column 22, lines 38-40).
- i. Referring to Claim 9, Kucharczyk discloses wherein a density is obtained by a numerical simulation process (column 11, line 65).

- j. Referring to Claim 10, Kucharczyk discloses wherein a density is obtained by an algorithm specification (column 11, line 65).
- k. With regard to Claim 11, the claim is not examined because it is dependent upon one of the unselected services.
- l. With regard to Claim 12, the claim is not examined because it is dependent upon one of the unselected services.
- m. With regard to Claim 13, the claim is not examined because it is dependent upon one of the unselected services.
- n. With regard to Claim 14, the claim is not examined because it is dependent upon one of the unselected services.
- o. With regard to Claim 15, the claim is not examined because it is dependent upon one of the unselected services.
- p. With regard to Claim 16, the claim is not examined because it is dependent upon one of the unselected services.
- q. With regard to Claim 17, the claim is not examined because it is dependent upon one of the unselected services.
- r. With regard to Claim 18, the claim is not examined because it is dependent upon one of the unselected services.
- s. With regard to Claim 19, the claim is not examined because it is dependent upon one of the unselected services.

- t. Referring to Claim 20, Kucharczyk discloses wherein said density comprises a concentration of a drug or other molecular substance in an organism (column 6, line 60).
- u. Referring to Claim 21, Kucharczyk discloses wherein said density refers to the concentration of a class of cell in an organism (column 6, line 63).
- v. Referring to Claim 22, Kucharczyk discloses wherein said density refers to the concentration of microscopic devices inserted to an organism (column 6, line 61).
- w. Referring to Claim 23, Kucharczyk discloses wherein said organism is a human body (see figure 1).
- x. With regard to Claim 24, see explanation in Claim 23.
- y. With regard to Claim 25, see explanation in Claim 23.
- z. With regard to Claim 26, see explanation in Claim 23.
- aa. With regard to Claim 27, see explanation in Claim 23.
- bb. With regard to Claim 28, see explanation in Claim 23.
- cc. Referring to Claim 29, Kucharczyk discloses wherein the density represents molecules, cells or devices inserted into an organism, body or brain for therapeutic purposes (column 6, lines 60-64).
- dd. Referring to Claim 30, Kucharczyk discloses wherein density is obtained by simulation of the transport and action of said molecule, cells or devices (column 9, lines 22-27).

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- ee. Referring to Claim 31, Kucharczyk discloses wherein said density within the body, and said molecules or cells are part of a normal process of disease process (column 8, lines 25-26).
- ff. Referring to Claim 32, Kucharczyk discloses wherein said density refers to a material being transported by a geological process (column 8, lines 28-29).
- gg. Referring to Claim 33, Kucharczyk discloses wherein said density refers to a material moving through a structure created by human agency (see figure 2 for the structure).
- hh. Referring to Claim 34, wherein said density is a mathematical construct convenient in defining three-dimensional shapes for the purpose of computer aided design (column 7, lines 36-40).

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Lindall, U.S. Patent No. 5,470,307, see figure 10 and column 3.

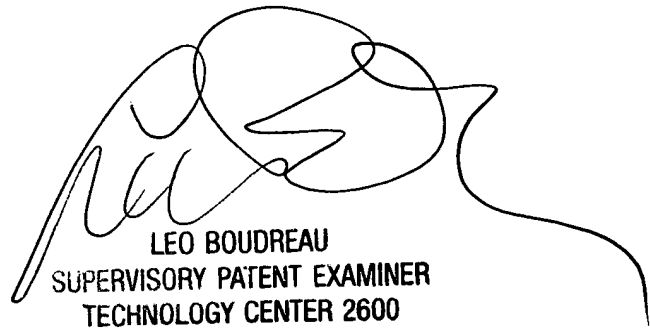
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tom Y Lu whose telephone number is (703) 306-4057. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tom Y. Lu



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